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EXAMINER

TOTH, KAREN E

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/789,492

Applicant(s)

NECOLA SHEHADA ET AL.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6-14, 28-53, 57, 58, 64 and 71-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 15-27, 54-56, 59-61, 63, 65-67, 69 is/are rejected.
- 7) ☒ Claim(s) 62, 68, 70 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 17 June 2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species:

2. Group A:

Species I, drawn to a system and method for monitoring tissue condition comprising a single device (claims 1-27, 55-56, 63, and 65-70).

Species II, drawn to a system and method for monitoring tissue condition comprising two devices (claims 28-53, 57-58, 64, and 71-74).

Group B

Species I, directed to a sensing system that senses temperature (claim 4).

Sub-species II, directed to a sensing system that senses oxygenation (claim 5).

Species III, directed to a sensing system that computes perfusion (claim 6).

Species IV, directed to a sensing system that senses color (claim 7).

Species V, directed to a sensing system that senses pH (claim 8).

Species VI, directed to a sensing system that senses NADH levels (claim 9).

Species VII, directed to a sensing system that senses prothrombin levels
(claim 10).

Species VIII, directed to a sensing system that senses biochemical
composition (claim 11).

Species IX, directed to a sensing system that computes drug
concentrations (claim 12).

Species X, directed to a sensing system that senses turgidity (claim 13).

Species XI, directed to a sensing system that senses pressure (claim 14).

3. The species of Group A are independent or distinct because the physical configuration of the system of Species II allows for measurement in two distant locations, while the configuration of Species I limits the available area for measurement to the immediate vicinity of the single device. The species of Group B are independent or distinct because each system requires a separate and distinct physical sensor to detect the desired parameter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 54 and 59-62 are generic.

Claims 55-58 and 63-66 were initially classified as generic during the telephone election. The examiner was mistaken. These claims are drawn to non-elected Species

II, because they require two devices for a method of monitoring tissue condition. The claims drawn to the non-elected invention have been treated as such in this action.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. During a telephone conversation with Marc Brown/Jessica Brown on May 5, 2006 and May 19 2006, a provisional election was made with traverse to prosecute Group A, Species I, Group B, species II, claims 1-3, 5, 15-27, 55-56, 63, and 65-70. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4, 6-14, 28-53, 57-58, 64, and 71-74 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

6. Claims 68 and 70 are objected to because of the following informalities: The phrase "the display" in each claim lacks antecedent basis. It is suggested that these be changed to --a display--. Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The phrase "external to the body" claims a positive relationship to the body.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 15, 18, 21, 23, 27, 54, 55, 56, 63, 65, 66, 67, 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Miesel'477 (US Patent 6106477).

Regarding Claim 1, Miesel'477 discloses a system comprising an implantable housing (element 10) including a first surface (element 15) and a second surface (element 11) both on the outside of the housing (column 5, lines 43-45); a first sensor for sensing a physiological tissue property proximate to the first surface (column 5, lines 54-55); a second sensor for sensing the same physiological tissue property proximate to the second surface (column 5, lines 3-7); and a processing system in communication with both sensors for computing a difference between the results of the physiological tissue property measurements (column 5, lines 5-7; column 7, lines 28-35 and 39-40).

Regarding Claim 3, Meisel'477 further discloses that the sensing surfaces may be on substantially opposite sides of the device (Figure 1).

Regarding Claim 15, the device of Miesel'477 may be used to deliver energy to the tissue proximate to the sensing surfaces, since oxygenation sensing (column 5, lines 19-21) comprises transmission of light.

Regarding Claim 18, Miesel'477 further discloses that the implantable device comprises a power source, electronics, and communications circuits (element 57; Figure 12).

Regarding Claim 21, Miesel'477 further discloses that the device may include an antenna for transmitting signals (column 11, lines 55-57).

Regarding Claim 23, Miesel'477 further discloses that the physiological tissue property being sensed may be temperature (column 5, lines 13-14); and that the system

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may be configured to calculate the difference between the first and second sensors (column 10, lines 31-40).

Regarding Claim 27, Miesel'477 further discloses that the device may comprise anchors (element 95; column 7, lines 13-17).

Regarding Claim 54, Miesel'477 discloses a method for measuring a physiological tissue property comprising receiving information from a first and a second sensor (column 5, lines 5-7; column 7, lines 28-35 and 39-40); calculating the difference between the first and second sensors (column 10, lines 31-40); and monitoring the data to evaluation the condition of a patient over time (column 8, lines 26-31).

Regarding Claim 55, the device of Miesel'477 may be oriented in such a way that the first sensor and the second sensor are monitoring physiological properties in different regions of the same tissue.

Regarding Claim 56, the device of Miesel'477 may be oriented in such a way that the first sensor and the second sensor are monitoring the physiological properties of different tissues.

Regarding Claim 63, the device of Miesel'477 is placed around a tissue (column 4, lines 47-58).

Regarding Claim 65, the device of Miesel'477 may be implanted during surgery.

Regarding Claim 66, the device of Miesel'477 may be implanted after surgery.

Regarding Claim 67, Miesel'477 discloses a method of tissue condition monitoring comprising implanting a device with two sensing systems configured to sense a physiological tissue property within a body near the tissue to be measured

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(column 5, lines 5-7; column 7, lines 28-35 and 39-40); and orienting the device so that the first sensor monitors a first region of the tissue, and the second sensor monitors a second region of the same tissue.

Regarding Claim 69, Miesel'477 discloses a method of tissue condition monitoring comprising implanting a device with two sensing systems configured to sense a physiological tissue property within a body near the tissue to be measured (column 5, lines 5-7; column 7, lines 28-35 and 39-40); and orienting the device so that the first sensor monitors a first tissue, and the second sensor monitors a second, different, tissue.

10. Claims 1, 2, 18-20, 22, 54-56, 65-67, and 69 are rejected under 35 U.S.C. 102(a) as being anticipated by Fitz'629 (US Patent Application Publication 2002/0183629).

Fitz'629 teaches a device having a single housing (element 20) comprising two sensors (elements 17 and 18) connected to a lower surface (see Figure 1); the device includes a signal processor (element 23) that is used to calculate the difference between the measurements obtained by the sensors (paragraph [0054]).

Regarding Claim 18, Fitz'629 further discloses that the processing system may be located within the housing (paragraph [0047]).

Regarding Claim 19, Fitz'629 further discloses that the processing system may be external (paragraph [0074]).

Regarding Claim 20, Fitz'629 further discloses that the system comprises an antenna (element 25) for transmitting signals (paragraph [0060]).

Regarding Claim 22, Fitz'629 further discloses that the system comprises an antenna (element 25) for receiving signals (paragraph [0056]).

Regarding Claim 54, Fitz'629 discloses a method comprising receiving information from two sensing systems that measure the same physical property of a tissue, processing the information to compute a difference, and monitoring the information over time (paragraph [0060]).

Regarding Claim 55, the system used in the method of Fitz'629 may be oriented in such a way that the two sensing systems are monitoring physical properties of different regions of the same tissue.

Regarding Claim 56, Fitz'629 further discloses monitoring one tissue with the first sensing system, and a different tissue with the second sensing system (paragraph [0024]).

Regarding Claim 65, the system used in the method of Fitz'629 may be implanted during surgery.

Regarding Claim 66, the system used in the method of Fitz'629 may be implanted after surgery.

Regarding Claim 67, Fitz'629 discloses implanting a device within a body in proximity to a tissue to be measured, where the device has two sensing systems that sense the same physiological property of the tissue (paragraphs [0042] and [0043]); and orienting the device so that the sensing systems monitor different regions of the same tissue.

Regarding Claim 69, Fitz'629 discloses implanting a device within a body, where the device has two sensing systems that sense the same physiological property of tissue (paragraphs [0042] and [0043]); where the device is oriented so that the sensing systems monitor two different tissues.

11. Claims 1, 5, 16-18, 20, 22, 24-27, 54-55, 59-61, 63, and 65-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Sun'536 (US Patent 6122536).

Regarding Claim 1, Sun'536 discloses a system comprising a housing configured to be implanted within the body (Figure 4) with two sensing surfaces on the outside of the housing (elements 30 and 34); a first sensing system to sense a physiological property of tissue proximate to the first surface (elements 30a-30c); a second sensing system to sense the same physiological property of tissue proximate to the second surface (elements 34a-34c); and a processing system (element 300) in communication with both sensing systems to compute the difference between the results (column 18, lines 11-16; column 20, lines 54-57).

Regarding Claim 5, Sun'536 further discloses that the physiological property being monitored is oxygenation (column 1, lines 15-17).

Regarding Claim 15, Sun'536 further discloses that the system comprises an element for transmitting energy to the tissue (column 8, lines 1-5).

Regarding Claim 16, Sun'536 further discloses that the system comprises a third sensing system (elements 32a-32c) that may be used to sense a physiological property

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that is different from that sensed by the first and second sensing systems (column 11, lines 14-21).

Regarding Claim 17, Sun'536 further discloses that the sensing systems are located behind optically transparent material (elements 46, 48, 50; column 11, lines 14-15 and 17-19).

Regarding Claim 18, Sun'536 further discloses that the processing system (element 16) is located within the housing (Figures 1 and 2).

Regarding Claim 20, Sun'536 further discloses that the system may comprise an antenna for receiving data (column 21, lines 13-14)

Regarding Claim 22, Sun'536 further discloses that the system may comprise an antenna for transmitting data (column 21, lines 8-10).

Regarding Claim 24, Sun'536 further discloses that the system comprises a display (elements 410 and 450) for showing information sensed by the sensing systems (column 20, lines 21-30).

Regarding Claim 25, the display of Sun'536 may be used to display data corresponding to a difference between the physiological property sensed by the sensing systems.

Regarding Claim 26, Sun'536 further discloses that the sensing systems may comprise optical fibers (column 11, lines 54-56).

Regarding Claim 27, Sun'536 further discloses that the system comprises a portion that anchors the device (element 42; figures 2-4).

Regarding Claim 54, Sun'536 discloses a method comprising receiving information from two sensing systems that are configured to sense the same physiological property of tissue, processing the information from the system to calculate a difference in information sensed, and monitoring the information over time (column 18, lines 11-16; column 20, lines 54-57).

Regarding Claim 55, Sun'536 further discloses that the device is implanted such that the sensing systems are configured to monitor different regions of the same tissue (Figure 2).

Regarding Claim 59, Sun'536 further discloses using a device to display the data calculated by the system (column 20, lines 21-30).

Regarding Claim 60, Sun'536 further discloses using a device to display a relationship between the data from the sensing systems (column 20, lines 21-30).

Regarding Claim 61, the difference between results is a form of correlation.

Regarding Claim 63, Sun'536 further discloses putting the device on the surface of a tissue (figure 1).

Regarding Claim 65, the system used in the method of Sun'526 may be implanted during surgery.

Regarding Claim 66, the system used in the method of Sun'526 may be implanted after surgery.

Regarding Claim 67, Sun'536 discloses a method comprising implanting a device with two sensing systems that measure the same physiological property of tissue

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(column 10, line 54, to column 11, line 21); and orienting the device such that the sensing systems measure different regions of the same tissue (Figure 4).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miesel'477 in view of Gord'848 (US Patent 5999848).

Regarding Claim 20, Miesel'477 discloses all the elements of the current invention, as applied to Claim 1, except for the system including an antenna for receiving power.

Gord'848 further teaches that the device may receive power signals (column 5, lines 34-36) in order to provide power for operation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel'477 with the power receiving capability of Gord'848, in order to provide power for operation.

Regarding Claim 22, Miesel'477 discloses all the elements of the current invention, as applied to Claim 1, except for the system including an antenna for receiving signals.

Gord'848 further teaches that the device may receive signals (column 5, lines 34-36) in order to control or modify operation of the device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel'477 with the signal receiving capability of Gord'848, in order to control or modify operation of the system.

14. Claims 19, 24, 25, 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miesel'477 in view of Hines'365 (US Patent 6582365).

Regarding Claim 19, Miesel'477 discloses all the elements of the current invention, as applied to Claim 1, except for the processing system being located outside the patient.

Hines'365 further teaches that the system includes a signal processing system (column 2, lines 52-54) that is located outside a patient (Figure 1), so that gathered data may be stored and processed for future reference.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel'477 with an external signal

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processing system, as taught by Hines'365, so that gathered data may be stored and processed for future reference.

Regarding Claim 24, Miesel'477 discloses all the elements of the current invention, as applied to Claim 1, except for the system including a display configured to show information gathered by the sensing systems.

Hines'365 further teaches that the system includes a display that is used to show the gathered physiological data (column 2, lines 52-54), in order to allow medical professionals to examine the results of the gathered physiological data.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel'477 with the display of Hines'365, in order to allow medical professionals to examine the results of the gathered physiological data.

Regarding Claim 25, Miesel'477 discloses all the elements of the current invention, as applied to Claim 1, except for the system including a display configured to show data corresponding to the difference between the signals gathered from the two sensing systems.

Miesel'477 further discloses that the system may be configured to calculate the difference between the first and second sensors (column 10, lines 31-40).

Hines'365 teaches that the system includes a display that is used to show gathered physiological data (column 2, lines 52-54), in order to give an indication of a patient's condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel'477 with the display of Hines'365 used to show data corresponding to the difference between the signals gathered by the sensing systems, in order to give an indication of a patient's condition.

Regarding Claim 59, Miesel'477 discloses all the elements of the current invention, as applied to Claim 54, except for the method comprising displaying data regarding the difference between the data gathered by the sensing systems.

Hines'365 further teaches that the system includes a display that is used to show the gathered physiological data (column 2, lines 52-54), in order to allow medical professionals to examine the results.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Miesel'477 with the display of the difference between the gathered data, as taught by Hines'365, in order to allow medical professionals to examine the results.

Regarding Claim 60, Miesel'477 discloses all the elements of the current invention, as applied to claim 54, except for calculating and displaying the difference between the measurements taken by the first and second sensors. Miesel'477 further discloses calculating the difference between the first and second sensors (column 10, lines 31-40), but does not disclose display of the data.

Hines'365 further teaches that the system includes a display that is used to show the gathered physiological data (column 2, lines 52-54), in order to allow medical professionals to examine the results.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have composed the method of Miesel'477 with the additional step of displaying the relationship of the gathered data, as taught by Hines'365, in order to allow medical professionals to examine the results.

Regarding Claim 61, Miesel'477 in view of Hines'365 discloses all the elements of the current invention; the difference between measured results is a form of correlation.

Allowable Subject Matter

15. Claims 62, 68, and 70 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the claimed structure as follows:

As to Claim 62, the prior art of record lacks the combination of method steps comprising receiving and processing sensing information from two sensing systems; monitoring the information over time; displaying the difference in sensed data from the systems; and positioning an icon on the display to show the position of the device within a body.

As to Claim 68, the prior art of record lacks the combination of method steps comprising implanting a device with two sensing systems within a body such that the sensing systems sense the same physiological property from two regions of the same

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tissue; and positioning an icon on a display to show the position of the device within a body.

As to Claim 70, the prior art of record lacks the combination of method steps comprising implanting a device with two sensing systems within a body such that the sensing systems sense the same physiological property from two different tissues; and positioning an icon on a display to show the position of the device within a body.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 4703756 to Gough, which discloses an implantable two-sensor system.

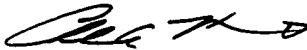
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Charles A. Marmor, II
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